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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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01/17/2002

Jian Ling Ding

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SANTA MONICA, CA 90404

EXAMINER

GHALLI, ISIS A D

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

08/31/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/053,387	Applicant(s) DING ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-8,10,13,16,18-32 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-8,10,13,16 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
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DETAILED ACTION

The receipt is acknowledged of applicants' request for RCE filed 05/15/2009.

Claims 1, 4, 9, 11, 12, 14, 15, 17, 33 and 34 have been canceled. Claims 40 and 41 are currently added.

Claims 2, 3, 5-8, 10, 13, 16, 18-32, 35-41 are pending.

This application contains claims 2, 3, 5-8, 10, 13, 16, 18-31 drawn to nonelected invention with traverse in the reply filed on 03/12/2004.

Claims 32, 35-41 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/15/2009 has been entered.

Specification

2. The use of the trademark "Royalene 521" and "Royalene 512" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32, 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 contains the trademark/trade name "Royalene 521". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods

associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe EPDM and, accordingly, the identification/description is indefinite. Applicants do not define the composition of Royalene 521 in terms of ingredients and amounts.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 32, 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Meyer et al. (US 4,738,257) and Balinth (US 4,335,026).

Applicant Claims

Claim 32 recites a hydrocolloid composition comprising: 521 8.4-15% Royalene 521 ethylene propylene diene monomer polymer comprising about 25% to 75% ethylene and about 75% to 25% propylene; up to about 95% polyisobutylene; about 20% to 40% hydrophilic particles; and up to about 35% plasticizer.

Claim 40 recites a hydrocolloid composition comprising: up to 70% ethylene propylene diene monomer polymer comprising about 25% to 75% ethylene and about 75% to 25% propylene; up to about 95% polyisobutylene; about 20% to 40% hydrophilic particles; and up to about 35% plasticizer; wherein the hydrocolloid composition has a saline absorption percentage of about 318 % to 351%.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Meyer teaches wound dressing comprises wound contact layer comprising elastomeric continuous phase with particulate water-absorbing hydrocolloid phase dispersed therein (abstract; col.5, lines 9-13). The wound dressing increases fluid absorption without including dislodgment and leakage and facilitates one piece removal with minimal wound irritation (col.2, 42-48; col.3, lines 27-30). The hydrocolloid particulate is selected from CMC, pectin, and karaya gum, and forms 40-60% of wound contacting layer (col.5, lines 40-55; col.6, lines 25-30). The elastomeric phase comprises 20-35% polyisobutylene (PIB), 5-25% cross-linker such as styrene-olefin-styrene that reads on styrenic block copolymer claimed by claim 37, 1-7% oils that read on plasticizer claimed by claim 32, and further comprises superabsorbent and/or fumed silica that read on additives claimed by claim 38 (col.5, lines 65-68; col.6, lines 1-12, 25-30, 38-47, 59-68; col.10, 44). The oils, superabsorbent, and petrolatum disclosed by the reference all read on therapeutic agents claimed by claim 35. The reference further teaches material to improve the dry tack of the composition comprising polymer of dicyclopentadiene (col.6, lines 53-57).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although Meyer suggests polymers of dicyclopentadiene wherein dicyclopentadiene reads on diene part of the polymer, and although the reference teaches elastomeric polymer forming the continuous phase, however, the reference

does not explicitly teach EPDM as polymer containing diene as required by claims 32 and 40.

Balinth teaches an adhesive composition for application to the skin as an adhesive bandage and tape suitable for covering wound and having decreased resistance to peel removal while maintaining high shear resistance in air and in water (abstract; col.1, lines 7-17; col.3, lines 50-55). The preferred adhesive composition comprises ethylene-propylene-diene monomer terpolymer wherein the ratio of ethylene to propylene is 3:1, i.e. 75% ethylene and 25% propylene (col.2, lines 57-61). The composition comprises 8.1 to 10.8 wt. % of EPDM (examples). The composition further comprises, styrene block copolymer in an amount of 25-42%, elastomer stabilizer, plasticizer, and anti-oxidants, which read on the active agent (col.2, lines 20-33, 42-44; col.3, lines 30-33; col.5, lines 27-29; col.5, examples I-III).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprises wound contact layer comprising elastomeric phase with particulate water-absorbing hydrocolloid phase dispersed therein wherein the elastomeric phase comprises PIB, particulate, plasticizer and polymer of dicyclopentadiene as taught by Meyer, and replace the polymer of dicyclopentadiene with EPDM polymer having 75% ethylene and 25% propylene taught by Balinth. One would have been motivated to do so because Balinth teaches that

adhesive comprising EPDM polymer having this ratio of ethylene and propylene is preferred and suitable for wound dressing, and provides decreased resistance to peel removal while maintaining high shear resistance in air and in water. One would reasonably expect formulating hydrocolloid adhesive composition comprising 8.1-10.8% EPDM polymer having ratio of ethylene to propylene of 3:1, 30-35% polyisobutylene, 30-60% hydrophilic particles, and 1-7% plasticizer, wherein the hydrocolloid adhesive composition is non-irritating to the skin and has decreased resistance to peel removal while maintaining high shear resistance in air and in water.

Regarding saline absorption as claimed by claim 40, the composition produced from the combination of the references is expected to have the same saline absorption capacity because the combination of the references teach hydrocolloid composition comprising 8.1-10.8% EPDM polymer having ratio of ethylene to propylene of 3:1, 30-35% polyisobutylene, 30-60% hydrophilic particles, and 1-7% plasticizer. In other words, the combination of the references teaches the claimed composition comprising the same ingredients in the same amounts, and it is expected for the produced composition to have the same properties since compounds and their properties are inseparable.

Regarding claim 41 that recites "the composition does not contain butyl rubber", it has been held that "Any negative limitation or exclusionary proviso must have basis in the original disclosure." See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977). In *In re Johnson*, the court noted that any negative limitation or exclusionary proviso *must have basis in the original disclosure*. Only if alternative elements are positively recited in the specification, they may be explicitly excluded in

the claims. In the present case the negative limitation/exclusionary proviso does not have basis in the original disclosure, and the alternative elements were not positively recited in the specification, they are generically disclosed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

9. Applicant's arguments filed 05/15/2009 have been fully considered but they are not persuasive.

Applicants argue that Table 2 of the present specification shows the preferred hydrocolloid compositions 8-11 having a percentage saline absorption of 318-351% whereas the US 4,551,490 prior art 4-7 show a percentage saline absorption of 209-251%. The increase of saline absorption from around 200% to 300% is a significant unexpected increase. The cited prior art does not teach saline absorption of 318-351% as claimed by claim 40. Applicants further argue that none of the cited references suggest the combination of EPDM and PIB to obtain the advantage of high absorption because EPDM polymer is hydrophobic and obtaining high absorption is not expected by one skilled in the art. As stated in the MPEP, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are

evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535,538, 152 USPQ 602, 604 (CCPA 1967).

In response to this argument, it is argued that the composition produced from the combination of the references (Meyer and Balin) is expected to have the same saline absorption capacity because the combination of the references teach hydrocolloid composition comprising 8.1-10.8% EPDM polymer having ratio of ethylene to propylene of 3:1, 30-35% polyisobutylene, 30-60% hydrophilic particles, and 1-7% plasticizer. In other words, the combination of the references teaches the claimed composition comprising the same ingredients in the same amounts, and it is expected for the produced composition to have the same properties since compounds and their properties are inseparable. The comparison data in the specification is between the present invention and US 4,551,490 that not included in the present rejection, and does not contain EPDM at all, while the combination of the cited references teaches hydrocolloid composition comprising EPDM as well as the other claimed ingredients.

In addition, regarding applicant's arguments of unexpected results in the instant specification, it is the examiner's position that the data in the specification regarding saline absorption are not unexpected results and therefore can not rebut prima facie obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected

beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

Furthermore, EPDM is hydrophobic polymer, it was not used by applicant for increasing the absorption of the composition. It is apparent that the elimination of butyl rubber was the cause of increased absorption ability of the composition. This is evident from Table 2, example 3, wherein the highest absorption of saline was obtained by higher PIB and absence of butyl rubber. Absence of PIB provided least saline absorption, as evident from Table 3, example 16. Applicants admit that EPDM is used to improve integrity of the composition. Nothing of record showing that EPDM has influence on the absorption property of the composition.

Minor Informalities

10. Claims 32 and 40 are objected to because of the following informalities: the word "polymer" in the 4th line of claim 32 and in the 3rd line of claim 40 is misspelled as "polyer". Appropriate correction is required.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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